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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,208	11/12/2003	Carol Ann Morris	CL/V-32765A	5997

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PATENT DEPARTMENT
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EXAMINER	
WOOD, AMANDA P	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,208	MORRIS ET AL.	
	Examiner	Art Unit	
	Amanda P. Wood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION-Final Rejection

The amendment filed 14 March 2006 was received and has been entered. Claims 1-6 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, there is inadequate support for the phrase "about 45 minutes" in line 9 of claim 1. Furthermore, the phrase "ratio...is about 1.5 or larger" in lines 13-14 of claim 1 also has inadequate support in the specification, and is therefore, considered new matter. All other claims depend directly or indirectly from claim 1 and are therefore also rejected for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over March (US 6,681,127) in view of Brzheskii et al (Derwent SU 1534406) and the American Diabetes Association (2002).

A method for rapidly screening for diabetes is claimed, wherein a glucose-sensing ophthalmic device is contacted with ocular fluid, first glucose concentration is obtained, a carbohydrate load is administered, a second glucose concentration is obtained, and the first and second glucose concentrations are compared to determine if a patient is diabetic.

March teaches a method of testing the concentration of an analyte (I.e., glucose) in ocular fluid (i.e., tears) wherein a glucose-sensing ophthalmic lens (i.e., device) is contacted with ocular fluid to determine the glucose concentration. March further teaches that the glucose-sensing ophthalmic lens testing agent composition comprises a receptor moiety with a binding site for the glucose and a competitor moiety wherein binding of the glucose or the competitor to the receptor binding site is reversible, wherein the amount of detectably labeled competitor that is displaced from the receptor by the glucose provides a means of determining the glucose concentration. March teaches that the competitor moiety comprises a detectable label, such as a fluorescent

label, and that it is most preferable that the detectable fluorescent label be more readily detectable when the competitor is not bound to the analyte/competitor binding site of the receptor. Therefore, when the fluorescently labeled competitor is not bound to the receptor binding site, (i.e., displaced by the analyte glucose) the fluorescence is unquenched, and when the competitor is bound to the receptor (i.e., not displaced by glucose) the fluorescence is quenched (see, for example, Abstract, col. 3, lines 10-55 and col. 4, lines 1-40, and col. 10, lines 30-45).

March does not specifically teach the method of taking a fasting glucose level, administering a glucose load, and then taking a second glucose level.

Brzheskii et al beneficially teach that diabetes can be diagnosed by giving a patient oral glucose in the amount of 1g/kg of body weight on an empty stomach, and after 60-90 minutes, or preferably 75 minutes, (the concentration of glucose in tears is determined.

The American Diabetes Association (ADA) published a position statement in January 2002 regarding the glucose concentration levels for diagnosis of diabetes. The fasting plasma glucose level for patients found to be diabetic is greater than or equal to 126 mg/dL, and the plasma glucose level for patients found to be diabetic after the 2 hour glucose tolerance test is greater than or equal to 200 mg/dL. Patients who are found to have these glucose levels are considered to be diabetic (see, for example, pg. S22). The ratio of the second glucose concentration over the fasting glucose concentration is about 1.59 (i.e., about 1.5 or larger).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the glucose-sensing ophthalmic device of March in a method to screen for diabetes based upon the beneficial teachings provided by the secondary reference with respect to the art-recognized method of taking a fasting glucose level, administering a glucose load, waiting for a specified period of time, and then taking a second glucose level. It was well-known to one of ordinary skill in the art at the time the claimed invention was made that diabetes can be diagnosed using a two or three hour oral glucose tolerance test, wherein a patient has a fasting glucose level taken, the patient drinks a glucose loaded beverage (normally 75g of glucose), waits about an hour, and then has glucose levels taken at specified intervals, usually every half to one hour up to 3 hours. In addition, the ADA specifically points out that the diagnosis of diabetes is based upon glucose concentrations of particular levels, and therefore one of ordinary skill in the art, with the knowledge that tear glucose tracks blood or plasma glucose, would have been motivated and equipped to determine the ratio for diagnosis of diabetes using a glucose-sensing ophthalmic device. Furthermore, the cited references particularly point out that glucose levels can be determined using tears, and therefore, it would have been both obvious and beneficial for the skilled artisan to use the methods taught by March and Brzheskii et al to screen for diabetes so as to avoid repeated needlesticks normally encountered in an oral glucose tolerance test. In addition, determining glucose concentration in tears after "about 45 minutes" in claim 1 could be interpreted to mean 60 minutes, as beneficially taught by Brzheskii et al. The result-effective adjustment of particular conventional working conditions (e.g.,

administering a particular amount of glucose, waiting for a particular amount of time, and/or using particular detectable optical signals) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 14 March 2006 have been fully considered but they are not persuasive. In particular, the Applicant argues that the cited references do not teach or suggest determining by means of a glucose-sensing ophthalmic device a second glucose concentration at a period of time from about 15 minutes to about 45 minutes after orally administering the load of carbohydrate. However, based upon the teachings of March (i.e, using a glucose-sensing ophthalmic device to determine glucose concentration in tears) and the teachings of Brzheskii et al, wherein a load of carbohydrate is given to a patient and a second glucose concentration is determined by means of a glucose-sensing ophthalmic device at 60 minutes (i.e., about 45 minutes) after administration of the load of carbohydrate, one of ordinary skill in the art would have been motivated to combine the glucose-sensing ophthalmic device of March and

the method of Brzheskii et al to rapidly screen patients for diabetes, as instantly claimed. Furthermore, Applicant argues that the cited references do not disclose or suggest anything about comparing the first and second glucose concentrations to determine if the ratio of the second glucose concentration over the first concentration is about 1.5 or larger, indicating that a patient is likely to be a diabetic. The Examiner respectfully disagrees. It is well-known to one of ordinary skill in the art that during an oral glucose tolerance test, patients suspected of having diabetes are asked to fast, then a first glucose concentration is taken, then the patient is given an oral load of carbohydrate, and then a second glucose concentration is taken. Patients who are considered to be diabetic will have a fasting plasma glucose level of about 126 mg/dL and will have a plasma glucose level of 200 mg/dL or higher after the oral carbohydrate load has been administered in an oral glucose tolerance test. The ratio of the second glucose concentration over the first is about 1.5, or larger, for patients who are diabetic, and therefore, it would have been obvious to one of ordinary skill in the art to use the device of March and the method of Brzheskii et al to determine whether patients are likely to be diabetic, based upon the knowledge that a patient whose second glucose concentration is about 1.5 larger than his fasting glucose concentration suggests that he is likely to be diabetic, according to the American Diabetes Association's Position Statement (see, for example, pg. S22, Table 2).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. P. Wood
Examiner
Art Unit 1655

APW

CHRISTOPHER R. TATE
PRIMARY EXAMINER